Calendar No. 90

105TH CONGRESS
1ST SESSION

S. 648

[Report No. 105–32]

A BILL

To establish legal standards and procedures for product liability litigation, and for other purposes.

JUNE 19, 1997

Reported without amendment

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To establish legal standards and procedures for product liability litigation, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 24, 1997

Mr. GORTON (for himself, Mr. ASHCROFT, Mr. MCCAIN, Mr. LOTT, Mr. ABRAHAM, Mr. ENZI, and Mr. INHOFE) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

JUNE 19, 1997

Reported by Mr. MCCAIN, without amendment

A BILL

To establish legal standards and procedures for product liability litigation, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Product Liability Reform Act of 1997''.

(b) TABLE OF CONTENTS.—The table of contents is as follows:

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—The Congress finds that—

(1) our Nation is overly litigious, the civil justice system is overcrowded, sluggish, and excessively costly and the costs of lawsuits, both direct and indirect, are inflicting serious and unnecessary injury on the national economy;

(2) excessive, unpredictable, and often arbitrary damage awards and unfair allocations of liability

have a direct and undesirable effect on interstate commerce by increasing the cost and decreasing the availability of goods and services;

(3) the rules of law governing product liability actions, damage awards, and allocations of liability have evolved inconsistently within and among the States, resulting in a complex, contradictory, and uncertain regime that is inequitable to both plaintiffs and defendants and unduly burdens interstate commerce;

(4) as a result of excessive, unpredictable, and often arbitrary damage awards and unfair allocations of liability, consumers have been adversely affected through the withdrawal of products, producers, services, and service providers from the marketplace, and from excessive liability costs passed on to them through higher prices;

(5) excessive, unpredictable, and often arbitrary damage awards and unfair allocations of liability jeopardize the financial well-being of many individuals as well as entire industries, particularly the Nation's small businesses and adversely affects government and taxpayers;

(6) the excessive costs of the civil justice system undermine the ability of American companies to

compete internationally, and serve to decrease the number of jobs and the amount of productive capital in the national economy;

(7) the unpredictability of damage awards is inequitable to both plaintiffs and defendants and has added considerably to the high cost of liability insurance, making it difficult for producers, consumers, volunteers, and nonprofit organizations to protect themselves from liability with any degree of confidence and at a reasonable cost;

(8) because of the national scope of the problems created by the defects in the civil justice system, it is not possible for the States to enact laws that fully and effectively respond to those problems;

(9) it is the constitutional role of the national government to remove barriers to interstate commerce and to protect due process rights; and

(10) there is a need to restore rationality, certainty, and fairness to the civil justice system in order to protect against excessive, arbitrary, and uncertain damage awards and to reduce the volume, costs, and delay of litigation.

(b) PURPOSES.—Based upon the powers contained in Article I, Section 8, Clause 3 and the Fourteenth Amendment of the United States Constitution, the purposes of

this Act are to promote the free flow of goods and services and to lessen burdens on interstate commerce and to uphold constitutionally protected due process rights by—

(1) establishing certain uniform legal principles of product liability which provide a fair balance among the interests of product users, manufacturers, and product sellers;

(2) placing reasonable limits on damages over and above the actual damages suffered by a claimant;

(3) ensuring the fair allocation of liability in civil actions;

(4) reducing the unacceptable costs and delays of our civil justice system caused by excessive litigation which harm both plaintiffs and defendants; and

(5) establishing greater fairness, rationality, and predictability in the civil justice system.

TITLE I—PRODUCT LIABILITY REFORM

SEC. 101. DEFINITIONS.

For purposes of this title—

(1) ACTUAL MALICE.—The term ''actual malice'' means specific intent to cause serious physical injury, illness, disease, death, or damage to property.

(2) CLAIMANT.—The term ''claimant'' means any person who brings an action covered by this title and any person on whose behalf such an action is brought. If such an action is brought through or on behalf of an estate, the term includes the claimant's decedent. If such an action is brought through or on behalf of a minor or incompetent, the term includes the claimant's legal guardian.

(3) CLEAR AND CONVINCING EVIDENCE.—The term ''clear and convincing evidence'' is that measure or degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established. The level of proof required to satisfy such standard is more than that required under preponderance of the evidence, but less than that required for proof beyond a reasonable doubt.

(4) COMMERCIAL LOSS.—The term ''commercial loss'' means any loss or damage solely to a product itself, loss relating to a dispute over its value, or consequential economic loss, the recovery of which is governed by the Uniform Commercial Code or analogous State commercial or contract law.

(5) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means damages awarded for economic and non-economic loss.

(6) ECONOMIC LOSS.—The term ''economic loss'' means any pecuniary loss resulting from harm (including the loss of earnings or other benefits related to employment, medical expense loss, replacement services loss, loss due to death, burial costs, and loss of business or employment opportunities) to the extent recovery for such loss is allowed under applicable State law.

(7) HARM.—The term ''harm'' means any physical injury, illness, disease, or death or damage to property caused by a product. The term does not include commercial loss.

(8) MANUFACTURER.—The term ''manufacturer'' means—

(A) any person who is engaged in a business to produce, create, make, or construct any product (or component part of a product) and who (i) designs or formulates the product (or component part of the product), or (ii) has engaged another person to design or formulate the product (or component part of the product);

(B) a product seller, but only with respect to those aspects of a product (or component part of a product) which are created or affected when, before placing the product in the stream of commerce, the product seller produces, creates, makes or constructs and designs, or formulates, or has engaged another person to design or formulate, an aspect of the product (or component part of the product) made by another person; or

(C) any product seller not described in subparagraph (B) which holds itself out as a manufacturer to the user of the product.

(9) NONECONOMIC LOSS.—The term ''noneconomic loss'' means subjective, nonmonetary loss resulting from harm, including pain, suffering, inconvenience, mental suffering, emotional distress, loss of society and companionship, loss of consortium, injury to reputation, and humiliation.

(10) PERSON.—The term ''person'' means any individual, corporation, company, association, firm, partnership, society, joint stock company, or any other entity (including any governmental entity).

(11) PRODUCT.—

(A) IN GENERAL.—The term ''product'' means any object, substance, mixture, or raw material in a gaseous, liquid, or solid state which—

(i) is capable of delivery itself or as an assembled whole, in a mixed or combined state, or as a component part or ingredient;

(ii) is produced for introduction into trade or commerce;

(iii) has intrinsic economic value; and

(iv) is intended for sale or lease to persons for commercial or personal use.

(B) EXCLUSIONS.—The term does not include—

(i) tissue, organs, blood, and blood products used for therapeutic or medical purposes, except to the extent that such tissue, organs, blood, and blood products (or the provision thereof) are subject, under applicable State law, to a standard of liability other than negligence; or

(ii) electricity, water delivered by a utility, natural gas, or steam.

(12) PRODUCT LIABILITY ACTION.—The term ''product liability action'' means a civil action brought on any theory for harm caused by a product.

(13) PRODUCT SELLER.—

(A) IN GENERAL.—The term ''product seller'' means a person who in the course of a business conducted for that purpose—

(i) sells, distributes, rents, leases, prepares, blends, packages, labels, or otherwise is involved in placing a product in the stream of commerce; or

(ii) installs, repairs, refurbishes, reconditions, or maintains the harm-causing aspect of the product.

(B) EXCLUSION.—The term ''product seller'' does not include—

(i) a seller or lessor of real property;

(ii) a provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who—

(I) acts in only a financial capacity with respect to the sale of a product; or

(II) leases a product under a lease arrangement in which the lessor does not initially select the leased product and does not during the lease term ordinarily control the daily operations and maintenance of the product.

(14) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded against any person or entity to punish or deter such person or entity, or others, from engaging in similar behavior in the future.

(15) STATE.—The term ''State'' means any State of the United States, the District of Columbia, Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and any other territory or possession of the United States or any political subdivision of any of the foregoing.

SEC. 102. APPLICABILITY; PREEMPTION.

(a) PREEMPTION.—

(1) IN GENERAL.—This Act governs any product liability action brought in any State or Federal court on any theory for harm caused by a product.

(2) ACTIONS EXCLUDED.—A civil action brought for commercial loss shall be governed only by applicable commercial or contract law.

(b) RELATIONSHIP TO STATE LAW.—This title supersedes State law only to the extent that State law applies to an issue covered by this title. Any issue that is not governed by this title, including any standard of liability applicable to a manufacturer, shall be governed by otherwise applicable State or Federal law.

(c) EFFECT ON OTHER LAW.—Nothing in this Act shall be construed to—

(1) waive or affect any defense of sovereign immunity asserted by any State under any law;

(2) supersede or alter any Federal law;

(3) waive or affect any defense of sovereign immunity asserted by the United States;

(4) affect the applicability of any provision of chapter 97 of title 28, United States Code;

(5) preempt State choice-of-law rules with respect to claims brought by a foreign nation or a citizen of a foreign nation;

(6) affect the right of any court to transfer venue or to apply the law of a foreign nation or to dismiss a claim of a foreign nation or of a citizen of a foreign nation on the ground of inconvenient forum; or

(7) supersede or modify any statutory or common law, including any law providing for an action to abate a nuisance, that authorizes a person to institute an action for civil damages or civil penalties, cleanup costs, injunctions, restitution, cost recovery, punitive damages, or any other form of relief for remediation of the environment (as defined in section 101(8) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601(8)).

(d) ACTIONS FOR NEGLIGENT ENTRUSTMENT.—A civil action for negligent entrustment, or any action brought under any theory of dramshop or third-party liability arising out of the sale or provision of alcohol products to intoxicated persons or minors, shall not be subject to the provisions of this Act but shall be subject to any applicable State law.

SEC. 103. LIABILITY RULES APPLICABLE TO PRODUCT SELLERS, RENTERS, AND LESSORS.

(a) GENERAL RULE.—

(1) IN GENERAL.—In any product liability action, a product seller other than a manufacturer shall be liable to a claimant only if the claimant establishes—

(A) that—

(i) the product that allegedly caused the harm that is the subject of the complaint was sold, rented, or leased by the product seller;

(ii) the product seller failed to exercise reasonable care with respect to the product; and

(iii) the failure to exercise reasonable care was a proximate cause of harm to the claimant;

(B) that—

(i) the product seller made an express warranty applicable to the product that allegedly caused the harm that is the subject of the complaint, independent of any express warranty made by a manufacturer as to the same product;

(ii) the product failed to conform to the warranty; and

(iii) the failure of the product to conform to the warranty caused harm to the claimant; or

(C) that—

(i) the product seller engaged in intentional wrongdoing, as determined under applicable State law; and

(ii) such intentional wrongdoing was a proximate cause of the harm that is the subject of the complaint.

(2) REASONABLE OPPORTUNITY FOR INSPECTION.—For purposes of paragraph (1)(A)(ii), a product seller shall not be considered to have failed to exercise reasonable care with respect to a product based upon an alleged failure to inspect the product—

(A) if the failure occurred because there was no reasonable opportunity to inspect the product; or

(B) if the inspection, in the exercise of reasonable care, would not have revealed the aspect of the product which allegedly caused the claimant's harm.

(b) SPECIAL RULE.—

(1) IN GENERAL.—A product seller shall be deemed to be liable as a manufacturer of a product for harm caused by the product if—

(A) the manufacturer is not subject to service of process under the laws of any State in which the action may be brought; or

(B) the court determines that the claimant would be unable to enforce a judgment against the manufacturer.

(2) STATUTE OF LIMITATIONS.—For purposes of this subsection only, the statute of limitations applicable to claims asserting liability of a product seller as a manufacturer shall be tolled from the date of the filing of a complaint against the manufacturer to the date that judgment is entered against the manufacturer.

(c) RENTED OR LEASED PRODUCTS.—

(1) Notwithstanding any other provision of law, any person engaged in the business of renting or leasing a product (other than a person excluded from the definition of product seller under section 101(13)(B)) shall be subject to liability in a product liability action under subsection (a), but any person engaged in the business of renting or leasing a product shall not be liable to a claimant for the tortious

act of another solely by reason of ownership of such product.

(2) For purposes of paragraph (1), and for determining the applicability of this title to any person subject to paragraph (1), the term ''product liability action'' means a civil action brought on any theory for harm caused by a product or product use.

SEC. 104. DEFENSE BASED ON CLAIMANT'S USE OF INTOXICATING ALCOHOL OR DRUGS.

(a) GENERAL RULE.—In any product liability action, it shall be a complete defense to such action if the defendant proves that—

(1) the claimant was intoxicated or was under the influence of intoxicating alcohol or any drug when the accident or other event which resulted in such claimant's harm occurred; and

(2) the claimant, as a result of the influence of the alcohol or drug, was more than 50 percent responsible for such accident or other event.

(b) CONSTRUCTION.—For purposes of subsection (a)—

(1) the determination of whether a person was intoxicated or was under the influence of intoxicating alcohol or any drug shall be made pursuant to applicable State law; and

(2) the term ''drug'' means any controlled substance as defined in the Controlled Substances Act (21 U.S.C. 802(6)) that was not legally prescribed for use by the claimant or that was taken by the claimant other than in accordance with the terms of a lawfully issued prescription.

SEC. 105. MISUSE OR ALTERATION.

(a) GENERAL RULE.—

(1) IN GENERAL.—In a product liability action, the damages for which a defendant is otherwise liable under Federal or State law shall be reduced by the percentage of responsibility for the claimant's harm attributable to misuse or alteration of a product by any person if the defendant establishes that such percentage of the claimant's harm was proximately caused by a use or alteration of a product—

(A) in violation of, or contrary to, a defendant's express warnings or instructions if the warnings or instructions are adequate as determined pursuant to applicable State law; or

(B) involving a risk of harm which was known or should have been known by the ordinary person who uses or consumes the product with the knowledge common to the class of per-

sons who used or would be reasonably anticipated to use the product.

(2) USE INTENDED BY A MANUFACTURER IS NOT MISUSE OR ALTERATION.—For the purposes of this Act, a use of a product that is intended by the manufacturer of the product does not constitute a misuse or alteration of the product.

(b) WORKPLACE INJURY.—Notwithstanding subsection (a), the damages for which a defendant is otherwise liable under State law shall not be reduced by the percentage of responsibility for the claimant's harm attributable to misuse or alteration of the product by the claimant's employer or any coemployee who is immune from suit by the claimant pursuant to the State law applicable to workplace injuries.

SEC. 106. UNIFORM TIME LIMITATIONS ON LIABILITY.

(a) STATUTE OF LIMITATIONS.—

(1) IN GENERAL.—Except as provided in paragraphs (2) and (3) and subsection (b), a product liability action may be filed not later than 2 years after the date on which the claimant discovered or, in the exercise of reasonable care, should have discovered—

(A) the harm that is the subject of the action; and

(B) the cause of the harm.

(2) EXCEPTION.—A person with a legal disability (as determined under applicable law) may file a product liability action not later than 2 years after the date on which the person ceases to have the legal disability.

(3) EFFECT OF STAY OR INJUNCTION.—If the commencement of a civil action that is subject to this title is stayed or enjoined, the running of the statute of limitations under this section shall be suspended until the end of the period that the stay or injunction is in effect.

(b) STATUTE OF REPOSE.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3), no product liability action that is subject to this Act concerning a product alleged to have caused harm (other than toxic harm) may be filed after the 18-year period beginning at the time of delivery of the product to the first purchaser or lessee.

(2) EXCEPTIONS.—

(A) A motor vehicle, vessel, aircraft, or train, that is used primarily to transport passengers for hire, shall not be subject to this subsection.

(B) Paragraph (1) does not bar a product liability action against a defendant who made an express warranty in writing as to the safety or life expectancy of the specific product involved which was longer than 18 years, but it will apply at the expiration of that warranty.

(c) TRANSITIONAL PROVISION RELATING TO EXTENSION OF PERIOD FOR BRINGING CERTAIN ACTIONS.—If any provision of subsection (a) or (b) shortens the period during which a product liability action could be otherwise brought pursuant to another provision of law, the claimant may, notwithstanding subsections (a) and (b), bring the product liability action not later than 1 year after the date of enactment of this Act.

SEC. 107. ALTERNATIVE DISPUTE RESOLUTION PROCEDURES.

(a) SERVICE OF OFFER.—A claimant or a defendant in a product liability action may, not later than 60 days after the service of—

(1) the initial complaint; or

(2) the applicable deadline for a responsive pleading;

whichever is later, serve upon an adverse party an offer to proceed pursuant to any voluntary, nonbinding alternative dispute resolution procedure established or recog-

nized under the law of the State in which the product liability action is brought or under the rules of the court in which such action is maintained.

(b) WRITTEN NOTICE OF ACCEPTANCE OR REJECTION.—Except as provided in subsection (c), not later than 10 days after the service of an offer to proceed under subsection (a), an offeree shall file a written notice of acceptance or rejection of the offer.

(c) EXTENSION.—The court may, upon motion by an offeree made prior to the expiration of the 10-day period specified in subsection (b), extend the period for filling a written notice under such subsection for a period of not more than 60 days after the date of expiration of the period specified in subsection (b). Discovery may be permitted during such period.

SEC. 108. UNIFORM STANDARDS FOR AWARD OF PUNITIVE DAMAGES.

(a) GENERAL RULE.—Punitive damages may, to the extent permitted by applicable State law, be awarded against a defendant if the claimant establishes by clear and convincing evidence that conduct carried out by the defendant with a conscious, flagrant indifference to the rights or safety of others was the proximate cause of the harm that is the subject of the action in any product liability action.

(b) LIMITATION ON AMOUNT.—

(1) IN GENERAL.—The amount of punitive damages that may be awarded in an action described in subsection (a) may not exceed the greater of—

(A) 2 times the sum of the amount awarded to the claimant for economic loss and noneconomic loss; or

(B) $250,000.

(2) SPECIAL RULE.—Notwithstanding paragraph (1), in any action described in subsection (a) against an individual whose net worth does not exceed $500,000 or against an owner of an unincorporated business, or any partnership, corporation, association, unit of local government, or organization which has fewer that 25 full-time employees, the punitive damages shall not exceed the lesser of—

(A) 2 times the sum of the amount awarded to the claimant for economic loss and noneconomic loss; or

(B) $250,000.

For the purpose of determining the applicability of this paragraph to a corporation, the number of employees of a subsidiary or wholly-owned corporation shall include all employees of a parent or sister corporation.

(3) EXCEPTION FOR INSUFFICIENT AWARD IN CASES OF EGREGIOUS CONDUCT.—

(A) DETERMINATION BY COURT.—If the court makes a determination, after considering each of the factors in subparagraph (B), that the application of paragraph (1) would result in an award of punitive damages that is insufficient to punish the egregious conduct of the defendant against whom the punitive damages are to be awarded or to deter such conduct in the future, the court shall determine the additional amount of punitive damages (referred to in this paragraph as the ''additional amount'') in excess of the amount determined in accordance with paragraph (1) to be awarded against the defendant in a separate proceeding in accordance with this paragraph.

(B) FACTORS FOR CONSIDERATION.—In any proceeding under paragraph (A), the court shall consider—

(i) the extent to which the defendant acted with actual malice;

(ii) the likelihood that serious harm would arise from the conduct of the defendant;

(iii) the degree of the awareness of the defendant of that likelihood;

(iv) the profitability of the misconduct to the defendant;

(v) the duration of the misconduct and any concurrent or subsequent concealment of the conduct by the defendant;

(vi) the attitude and conduct of the defendant upon the discovery of the misconduct and whether the misconduct has terminated;

(vii) the financial condition of the defendant; and

(viii) the cumulative deterrent effect of other losses, damages, and punishment suffered by the defendant as a result of the misconduct, reducing the amount of punitive damages on the basis of the economic impact and severity of all measures to which the defendant has been or may be subjected, including—

(I) compensatory and punitive damage awards to similarly situated claimants;

(II) the adverse economic effect of stigma or loss of reputation;

(III) civil fines and criminal and administrative penalties; and

(IV) stop sale, cease and desist, and other remedial or enforcement orders.

(C) REQUIREMENTS FOR AWARDING ADDITIONAL AMOUNT.—If the court awards an additional amount pursuant to this subsection, the court shall state its reasons for setting the amount of the additional amount in findings of fact and conclusions of law.

(D) PREEMPTION.—This section does not create a cause of action for punitive damages and does not preempt or supersede any State or Federal law to the extent that such law would further limit the award of punitive damages. Nothing in this subsection shall modify or reduce the ability of courts to order remittiturs.

(4) APPLICATION BY COURT.—This subsection shall be applied by the court and application of this subsection shall not be disclosed to the jury. Nothing in this subsection shall authorize the court to enter

an award of punitive damages in excess of the jury's initial award of punitive damages.

(c) BIFURCATION AT REQUEST OF ANY PARTY.—

(1) IN GENERAL.—At the request of any party the trier of fact in any action that is subject to this section shall consider in a separate proceeding, held subsequent to the determination of the amount of compensatory damages, whether punitive damages are to be awarded for the harm that is the subject of the action and the amount of the award.

(2) INADMISSIBILITY OF EVIDENCE RELATIVE ONLY TO A CLAIM OF PUNITIVE DAMAGES IN A PROCEEDING CONCERNING COMPENSATORY DAMAGES.—If any party requests a separate proceeding under paragraph (1), in a proceeding to determine whether the claimant may be awarded compensatory damages, any evidence, argument, or contention that is relevant only to the claim of punitive damages, as determined by applicable State law, shall be inadmissible.

SEC. 109. LIABILITY FOR CERTAIN CLAIMS RELATING TO DEATH.

In any civil action in which the alleged harm to the claimant is death and, as of the effective date of this Act, the applicable State law provides, or has been construed

to provide, for damages only punitive in nature, a defendant may be liable for any such damages without regard to section 108, but only during such time as the State law so provides. This section shall cease to be effective September 1, 1997.

SEC. 110. SEVERAL LIABILITY FOR NONECONOMIC LOSS.

(a) GENERAL RULE.—In a product liability action, the liability of each defendant for noneconomic loss shall be several only and shall not be joint.

(b) AMOUNT OF LIABILITY.—

(1) IN GENERAL.—Each defendant shall be liable only for the amount of noneconomic loss allocated to the defendant in direct proportion to the percentage of responsibility of the defendant (determined in accordance with paragraph (2)) for the harm to the claimant with respect to which the defendant is liable. The court shall render a separate judgment against each defendant in an amount determined pursuant to the preceding sentence.

(2) PERCENTAGE OF RESPONSIBILITY.—For purposes of determining the amount of noneconomic loss allocated to a defendant under this section, the trier of fact shall determine the percentage of responsibility of each person responsible for the claim-

ant's harm, whether or not such person is a party to the action.

TITLE II—BIOMATERIALS ACCESS ASSURANCE

SEC. 201. SHORT TITLE.

This title may be cited as the ''Biomaterials Access Assurance Act of 1997''.

SEC. 202. FINDINGS.

Congress finds that—

(1) each year millions of citizens of the United States depend on the availability of lifesaving or life enhancing medical devices, many of which are permanently implantable within the human body;

(2) a continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of the supply of the devices;

(3) most of the medical devices are made with raw materials and component parts that—

(A) are not designed or manufactured specifically for use in medical devices; and

(B) come in contact with internal human tissue;

(4) the raw materials and component parts also are used in a variety of nonmedical products;

(5) because small quantities of the raw materials and component parts are used for medical devices, sales of raw materials and component parts for medical devices constitute an extremely small portion of the overall market for the raw materials and medical devices;

(6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), manufacturers of medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the products are properly designed and have adequate warnings or instructions;

(7) notwithstanding the fact that raw materials and component parts suppliers do not design, produce, or test a final medical device, the suppliers have been the subject of actions alleging inadequate—

(A) design and testing of medical devices manufactured with materials or parts supplied by the suppliers; or

(B) warnings related to the use of such medical devices;

(8) even though suppliers of raw materials and component parts have very rarely been held liable in such actions, such suppliers have ceased supplying

certain raw materials and component parts for use in medical devices because the costs associated with litigation in order to ensure a favorable judgment for the suppliers far exceeds the total potential sales revenues from sales by such suppliers to the medical device industry;

(9) unless alternate sources of supply can be found, the unavailability of raw materials and component parts for medical devices will lead to unavailability of lifesaving and life-enhancing medical devices;

(10) because other suppliers of the raw materials and component parts in foreign nations are refusing to sell raw materials or component parts for use in manufacturing certain medical devices in the United States, the prospects for development of new sources of supply for the full range of threatened raw materials and component parts for medical devices are remote;

(11) it is unlikely that the small market for such raw materials and component parts in the United States could support the large investment needed to develop new suppliers of such raw materials and component parts;

(12) attempts to develop such new suppliers would raise the cost of medical devices;

(13) courts that have considered the duties of the suppliers of the raw materials and component parts have generally found that the suppliers do not have a duty—

(A) to evaluate the safety and efficacy of the use of a raw material or component part in a medical device; and

(B) to warn consumers concerning the safety and effectiveness of a medical device;

(14) attempts to impose the duties referred to in subparagraphs (A) and (B) of paragraph (13) on suppliers of the raw materials and component parts would cause more harm than good by driving the suppliers to cease supplying manufacturers of medical devices; and

(15) in order to safeguard the availability of a wide variety of lifesaving and life-enhancing medical devices, immediate action is needed—

(A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppli-

ers in such manner as to minimize litigation costs.

SEC. 203. DEFINITIONS.

As used in this title:

(1) BIOMATERIALS SUPPLIER.—

(A) IN GENERAL.—The term ''biomaterials supplier'' means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.

(B) PERSONS INCLUDED.—Such term includes any person who—

(i) has submitted master files to the Secretary for purposes of premarket approval of a medical device; or

(ii) licenses a biomaterials supplier to produce component parts or raw materials.

(2) CLAIMANT.—

(A) IN GENERAL.—The term ''claimant'' means any person who brings a civil action, or on whose behalf a civil action is brought, arising from harm allegedly caused directly or indirectly by an implant, including a person other than the individual into whose body, or in contact with whose blood or tissue, the implant is

placed, who claims to have suffered harm as a result of the implant.

(B) ACTION BROUGHT ON BEHALF OF AN ESTATE.—With respect to an action brought on behalf of or through the estate of an individual into whose body, or in contact with whose blood or tissue the implant is placed, such term includes the decedent that is the subject of the action.

(C) ACTION BROUGHT ON BEHALF OF A MINOR OR INCOMPETENT.—With respect to an action brought on behalf of or through a minor or incompetent, such term includes the parent or guardian of the minor or incompetent.

(D) EXCLUSIONS.—Such term does not include—

(i) a provider of professional health care services, in any case in which—

(I) the sale or use of an implant is incidental to the transaction; and

(II) the essence of the transaction is the furnishing of judgment, skill, or services;

(ii) a person acting in the capacity of a manufacturer, seller, or biomaterials supplier;

(iii) a person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel, except that—

(I) neither the exclusion provided by this clause nor any other provision of this Act may be construed as a finding that silicone gel (or any other form of silicone) may or may not cause harm; and

(II) the existence of the exclusion under this clause may not—

(aa) be disclosed to a jury in any civil action or other proceeding; and

(bb) except as necessary to establish the applicability of this Act, otherwise be presented in any civil action or other proceeding; or

(iv) any person who acts in only a financial capacity with respect to the sale of an implant.

(3) COMPONENT PART.—

(A) IN GENERAL.—The term ''component part'' means a manufactured piece of an implant.

(B) CERTAIN COMPONENTS.—Such term includes a manufactured piece of an implant that—

(i) has significant non-implant applications; and

(ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant.

(4) HARM.—

(A) IN GENERAL.—The term ''harm'' means—

(i) any injury to or damage suffered by an individual;

(ii) any illness, disease, or death of that individual resulting from that injury or damage; and

(iii) any loss to that individual or any other individual resulting from that injury or damage.

(B) EXCLUSION.—The term does not include any commercial loss or loss of or damage to an implant.

(5) IMPLANT.—The term ''implant'' means—

(A) a medical device that is intended by the manufacturer of the device—

(i) to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days; or

(ii) to remain in contact with bodily fluids or internal human tissue through a surgically produced opening for a period of less than 30 days; and

(B) suture materials used in implant procedures.

(6) MANUFACTURER.—The term ''manufacturer'' means any person who, with respect to an implant—

(A) is engaged in the manufacture, preparation, propagation, compounding, or processing (as defined in section 510(a)(1)) of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)) of the implant; and

(B) is required—

(i) to register with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section; and

(ii) to include the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section.

(7) MEDICAL DEVICE.—The term ''medical device'' means a device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) and includes any device component of any combination product as that term is used in section 503(g) of such Act (21 U.S.C. 353(g)).

(8) RAW MATERIAL.—The term ''raw material'' means a substance or product that—

(A) has a generic use; and

(B) may be used in an application other than an implant.

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(10) SELLER.—

(A) IN GENERAL.—The term ''seller'' means a person who, in the course of a business conducted for that purpose, sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce.

(B) EXCLUSIONS.—The term does not include—

(i) a seller or lessor of real property;

(ii) a provider of professional services, in any case in which the sale or use of an implant is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who acts in only a financial capacity with respect to the sale of an implant.

SEC. 204. GENERAL REQUIREMENTS; APPLICABILITY; PREEMPTION.

(a) GENERAL REQUIREMENTS.—

(1) IN GENERAL.—In any civil action covered by this title, a biomaterials supplier may raise any defense set forth in section 205.

(2) PROCEDURES.—Notwithstanding any other provision of law, the Federal or State court in which a civil action covered by this title is pending shall, in connection with a motion for dismissal or judgment based on a defense described in paragraph (1), use the procedures set forth in section 206.

(b) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (2), notwithstanding any other provision of law, this title applies to any civil action brought by a claimant, whether in a Federal or State court, against a manufacturer, seller, or biomaterials supplier, on the basis of any legal theory, for harm allegedly caused by an implant.

(2) EXCLUSION.—A civil action brought by a purchaser of a medical device for use in providing professional services against a manufacturer, seller, or biomaterials supplier for loss or damage to an implant or for commercial loss to the purchaser—

(A) shall not be considered an action that is subject to this title; and

(B) shall be governed by applicable commercial or contract law.

(c) SCOPE OF PREEMPTION.—

(1) IN GENERAL.—This title supersedes any State law regarding recovery for harm caused by an implant and any rule of procedure applicable to a civil action to recover damages for such harm only to the extent that this title establishes a rule of law applicable to the recovery of such damages.

(2) APPLICABILITY OF OTHER LAWS.—Any issue that arises under this title and that is not governed by a rule of law applicable to the recovery of damages described in paragraph (1) shall be governed by applicable Federal or State law.

(d) STATUTORY CONSTRUCTION.—Nothing in this title may be construed—

(1) to affect any defense available to a defendant under any other provisions of Federal or State law in an action alleging harm caused by an implant; or

(2) to create a cause of action or Federal court jurisdiction pursuant to section 1331 or 1337 of title 28, United States Code, that otherwise would not exist under applicable Federal or State law.

SEC. 205. LIABILITY OF BIOMATERIALS SUPPLIERS.

(a) IN GENERAL.—

(1) EXCLUSION FROM LIABILITY.—Except as provided in paragraph (2), a biomaterials supplier

shall not be liable for harm to a claimant caused by an implant.

(2) LIABILITY.—A biomaterials supplier that—

(A) is a manufacturer may be liable for harm to a claimant described in subsection (b);

(B) is a seller may be liable for harm to a claimant described in subsection (c); and

(C) furnishes raw materials or component parts that fail to meet applicable contractual requirements or specifications may be liable for harm to a claimant described in subsection (d).

(b) LIABILITY AS MANUFACTURER.—

(1) IN GENERAL.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the biomaterials supplier is the manufacturer of the implant.

(2) GROUNDS FOR LIABILITY.—The biomaterials supplier may be considered the manufacturer of the implant that allegedly caused harm to a claimant only if the biomaterials supplier—

(A)(i) has registered with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section; and

(ii) included the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section;

(B) is the subject of a declaration issued by the Secretary pursuant to paragraph (3) that states that the supplier, with respect to the implant that allegedly caused harm to the claimant, was required to—

(i) register with the Secretary under section 510 of such Act (21 U.S.C. 360), and the regulations issued under such section, but failed to do so; or

(ii) include the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section, but failed to do so; or

(C) is related by common ownership or control to a person meeting all the requirements described in subparagraph (A) or (B), if the court deciding a motion to dismiss in accordance with section 206(c)(3)(B)(i) finds, on the basis of affidavits submitted in accordance with section 206, that it is necessary to impose li-

ability on the biomaterials supplier as a manufacturer because the related manufacturer meeting the requirements of subparagraph (A) or (B) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(3) ADMINISTRATIVE PROCEDURES.—

(A) IN GENERAL.—The Secretary may issue a declaration described in paragraph (2)(B) on the motion of the Secretary or on petition by any person, after providing—

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

(B) DOCKETING AND FINAL DECISION.—Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 180 days after the petition is filed, the Secretary shall issue a final decision on the petition.

(C) APPLICABILITY OF STATUTE OF LIMITATIONS.—Any applicable statute of limitations shall toll during the period during which a claimant has filed a petition with the Secretary under this paragraph.

(c) LIABILITY AS SELLER.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant if—

(1) the biomaterials supplier—

(A) held title to the implant that allegedly caused harm to the claimant as a result of purchasing the implant after—

(i) the manufacture of the implant; and

(ii) the entrance of the implant in the stream of commerce; and

(B) subsequently resold the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 206(c)(3)(B)(ii) finds, on the basis of affidavits submitted in accordance with section 206, that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) LIABILITY FOR VIOLATING CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant, if the claimant in an action shows, by a preponderance of the evidence, that—

(1) the raw materials or component parts delivered by the biomaterials supplier either—

(A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for delivery of the product; or

(B) failed to meet any specifications that were—

(i) provided to the biomaterials supplier and not expressly repudiated by the biomaterials supplier prior to acceptance of delivery of the raw materials or component parts;

(ii)(I) published by the biomaterials supplier;

(II) provided to the manufacturer by the biomaterials supplier; or

(III) contained in a master file that was submitted by the biomaterials supplier

to the Secretary and that is currently maintained by the biomaterials supplier for purposes of premarket approval of medical devices; or

(iii) included in the submissions for purposes of premarket approval or review by the Secretary under section 510, 513, 515, or 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360, 360c, 360e, or 360j), and received clearance from the Secretary if such specifications were provided by the manufacturer to the biomaterials supplier and were not expressly repudiated by the biomaterials supplier prior to the acceptance by the manufacturer of delivery of the raw materials or component parts; and

(2) such conduct was an actual and proximate cause of the harm to the claimant.

SEC. 206. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS AGAINST BIOMATERIALS SUPPLIERS.

(a) MOTION TO DISMISS.—In any action that is subject to this title, a biomaterials supplier who is a defendant in such action may, at any time during which a motion

to dismiss may be filed under an applicable law, move to dismiss the action against it on the grounds that—

(1) the defendant is a biomaterials supplier; and

(2)(A) the defendant should not, for the purposes of—

(i) section 205(b), be considered to be a manufacturer of the implant that is subject to such section; or

(ii) section 205(c), be considered to be a seller of the implant that allegedly caused harm to the claimant; or

(B)(i) the claimant has failed to establish, pursuant to section 205(d), that the supplier furnished raw materials or component parts in violation of contractual requirements or specifications; or

(ii) the claimant has failed to comply with the procedural requirements of subsection (b).

(b) MANUFACTURER OF IMPLANT SHALL BE NAMED A PARTY.—The claimant shall be required to name the manufacturer of the implant as a party to the action, unless—

(1) the manufacturer is subject to service of process solely in a jurisdiction in which the biomate-

rials supplier is not domiciled or subject to a service of process; or

(2) an action against the manufacturer is barred by applicable law.

(c) PROCEEDING ON MOTION TO DISMISS.—The following rules shall apply to any proceeding on a motion to dismiss filed under this section:

(1) AFFIDAVITS RELATING TO LISTING AND DECLARATIONS.—

(A) IN GENERAL.—The defendant in the action may submit an affidavit demonstrating that defendant has not included the implant on a list, if any, filed with the Secretary pursuant to section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)).

(B) RESPONSE TO MOTION TO DISMISS.—In response to the motion to dismiss, the claimant may submit an affidavit demonstrating that—

(i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 205(b)(2)(B); or

(ii) the defendant who filed the motion to dismiss is a seller of the implant who is liable under section 205(c).

(2) EFFECT OF MOTION TO DISMISS ON DISCOVERY.—

(A) IN GENERAL.—If a defendant files a motion to dismiss under paragraph (1) or (2) of subsection (a), no discovery shall be permitted in connection to the action that is the subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss in accordance with the affidavits submitted by the parties in accordance with this section.

(B) DISCOVERY.—If a defendant files a motion to dismiss under subsection (a)(2)(B)(i) on the grounds that the biomaterials supplier did not furnish raw materials or component parts in violation of contractual requirements or specifications, the court may permit discovery, as ordered by the court. The discovery conducted pursuant to this subparagraph shall be limited to issues that are directly relevant to—

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

(3) AFFIDAVITS RELATING STATUS OF DEFENDANT.—

(A) IN GENERAL.—Except as provided in clauses (i) and (ii) of subparagraph (B), the court shall consider a defendant to be a biomaterials supplier who is not subject to an action for harm to a claimant caused by an implant, other than an action relating to liability for a violation of contractual requirements or specifications described in subsection (d).

(B) RESPONSES TO MOTION TO DISMISS.—The court shall grant a motion to dismiss any action that asserts liability of the defendant under subsection (b) or (c) of section 205 on the grounds that the defendant is not a manufacturer subject to such section 205(b) or seller subject to section 205(c), unless the claimant submits a valid affidavit that demonstrates that—

(i) with respect to a motion to dismiss contending the defendant is not a manufacturer, the defendant meets the applicable requirements for liability as a manufacturer under section 205(b); or

(ii) with respect to a motion to dismiss contending that the defendant is not a seller, the defendant meets the applicable requirements for liability as a seller under section 205(c).

(4) BASIS OF RULING ON MOTION TO DISMISS.—

(A) IN GENERAL.—The court shall rule on a motion to dismiss filed under subsection (a) solely on the basis of the pleadings of the parties made pursuant to this section and any affidavits submitted by the parties pursuant to this section.

(B) MOTION FOR SUMMARY JUDGMENT.—Notwithstanding any other provision of law, if the court determines that the pleadings and affidavits made by parties pursuant to this section raise genuine issues concerning material facts with respect to a motion concerning contractual requirements and specifications, the court may deem the motion to dismiss to be a motion for summary judgment made pursuant to subsection (d).

(d) SUMMARY JUDGMENT.—

(1) IN GENERAL.—

(A) BASIS FOR ENTRY OF JUDGMENT.—A biomaterials supplier shall be entitled to entry of judgment without trial if the court finds there is no genuine issue concerning any material fact for each applicable element set forth in paragraphs (1) and (2) of section 205(d).

(B) ISSUES OF MATERIAL FACT.—With respect to a finding made under subparagraph (A), the court shall consider a genuine issue of material fact to exist only if the evidence submitted by claimant would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

(2) DISCOVERY MADE PRIOR TO A RULING ON A MOTION FOR SUMMARY JUDGMENT.—If, under applicable rules, the court permits discovery prior to a ruling on a motion for summary judgment made pursuant to this subsection, such discovery shall be limited solely to establishing whether a genuine issue of material fact exists as to the applicable elements set forth in paragraphs (1) and (2) of section 205(d).

(3) DISCOVERY WITH RESPECT TO A BIOMATERIALS SUPPLIER.—A biomaterials supplier shall be

subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 205(d) or the failure to establish the applicable elements of section 205(d) solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties.

(e) STAY PENDING PETITION FOR DECLARATION.—If a claimant has filed a petition for a declaration pursuant to section 205(b)(3)(A) with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition.

(f) MANUFACTURER CONDUCT OF PROCEEDING.—The manufacturer of an implant that is the subject of an action covered under this title shall be permitted to file and conduct a proceeding on any motion for summary judgment or dismissal filed by a biomaterials supplier who is a defendant under this section if the manufacturer and any other defendant in such action enter into a valid and applicable contractual agreement under which the manufacturer agrees to bear the cost of such proceeding or to conduct such proceeding.

(g) ATTORNEY FEES.—The court shall require the claimant to compensate the biomaterials supplier (or a

manufacturer appearing in lieu of a supplier pursuant to subsection (f)) for attorney fees and costs, if—

(1) the claimant named or joined the biomaterials supplier; and

(2) the court found the claim against the biomaterials supplier to be without merit and frivolous.

TITLE III—LIMITATIONS ON APPLICABILITY; EFFECTIVE DATE

SEC. 301. EFFECT OF COURT OF APPEALS DECISIONS.

A decision by a Federal circuit court of appeals interpreting a provision of this Act (except to the extent that the decision is overruled or otherwise modified by the Supreme Court) shall be considered a controlling precedent with respect to any subsequent decision made concerning the interpretation of such provision by any Federal or State court within the geographical boundaries of the area under the jurisdiction of the circuit court of appeals.

SEC. 302. FEDERAL CAUSE OF ACTION PRECLUDED.

The district courts of the United States shall not have jurisdiction pursuant to this Act based on section 1331 or 1337 of title 28, United States Code.

SEC. 303. EFFECTIVE DATE.

This Act shall apply with respect to any action commenced on or after the date of the enactment of this Act

without regard to whether the harm that is the subject of the action or the conduct that caused the harm occurred before such date of enactment.

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